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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,875	03/02/2002	Hans Schuhbauer	HUBR-1206 (10202655)	4984

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,875	SCHUHBAUER ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 1/26/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27 – 31, 33, 34, 37, 40, 42, 43, 46 – 50 – 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich et al (USPN 5,691,379). The claims are drawn to a sustained release formulation of α-lipoic acid and/or derivative, a cationogenic polymer and an additional acidic component. The formulation further comprises fillers, and other excipients well known in the art.

Ulrich discloses a dihydrolipoic acid sustained release formulation comprising various biocompatible cellulosic polymers, acetic acid, and other fillers, lubricants and plasticizers known in the art (abstract; col. 48 – 64; col. 7, lin. 34 – col. 8, lin. 47). The formulation can be formed into medicaments such as capsules, pellets and pills, or in the form of a lotion (col. 9, lin. 42 – 48). The reference discloses methods for the administration of the formulation (col. 9, lin. 53 – col. 10, lin. 11). The formulation is granulated along with the carrier materials and processed at a temperature between 20 and 80 degrees Celsius (col. 10, lin. 23 – col. 11, lin. 3). These disclosures along with others render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 35, 36, 41, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al (USPN 5,691,379) in view or Ulrich et al (USPN 5,100,919). The claims are drawn to a sustained release formulation recited particular concentrations and proportions of the essential components, namely a cationogenic polymer, a α-lipoic acid and/or a derivative, and a further acid. The claims also are drawn to a method of production comprising combining the components along with other well known excipient such as filler, plasticizers and the like, wet granulating the combination and drying the granules between 5 and 50°C, an forming a tablet.

With regard to claims 35, 36 and 41, which recite limitations to specific concentrations, ratios and proportions, it is the position of the examiner that such limitations do not impart

patentability on the claims barring a showing of criticality. The prior art discloses a general combination of the elements, and applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claim 44, which recites the method of production, the reference discloses a similar procedure, yet does not disclose the proportion of part 1). It is the position of the examiner that though the reference does not disclose the particular proportions recited in the claims, a skilled artisan would still be motivated to follow the processing stapes of combining the active, with the excipients, granulating and drying them at a temperature between 20 and 80 °C, since wet granulation and tableting are so well known in the art. Ulrich '919 discloses tablets formed from wet granulation of the ingredients and drying overnight at a temperature of 45 °C (examples).

As discussed above the proportion of the active and inactive components could be determined through routine experimentation. With this in mind a skilled artisan would have been motivated by the suggestion of Ulrich '379 to granulated and dry the granules at the desired

temperature of Ulrich '919. It would have been obvious to combine the tablet the ingredients of Ulrich '379 with the process of Ulrich '919 with an expected result of a tablet with antioxidant properties.

5. Claims 32, 38, 39 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al (USPN 5,691,379) in view of Weithman et al (USPN 5,318,987), Bethge et al (USPN 5,621,117), Prigal (USPN 3,678,149) and Matsuoka et al (USPN 3,697,647). The claims are drawn to a pharmaceutical dosage form comprising a α-lipoic, a cationogenic polymer, and another acid. The α-lipoic acid can be present with cation such as iron, copper and palladium. The acid can be a Lewis acid, or a complex acid. The composition can be in the form of a food supplement as well.

As discussed above Ulrich discloses essential elements of the claimed invention. The reference discloses α-lipoic compound, biopolymer and secondary acid. Lacking in the reference are disclosures of the specific cations present in the active compound salt, the complex or Lewis acids, and the food supplement presentation.

Weithmann et al discloses an antioxidant composition comprising a α-lipoic acid derivative (col. 27, lin. 1). Cations present in the salts of the salts of the compound are alkaline earth metals such as zinc, iron and aluminum (col. 10, lin. 45 – 55). The composition further comprises further tableting excipients such as fillers sugars and tableting agents well known in the art (col. 12, lin. 5 – 34).

Bethge et al discloses a method for racemizing α-lipoic acid composition comprising inorganic and /or organic Lewis acids that are added to the α-lipoic compounds (col. 2, lin. 56 – 65; examples).

Prigal discloses a composition comprising hexacyanoiron in combination with antioxidants (col. 1, lin. 26 – col. 2, lin. 35; examples).

Matsuoka et al discloses a feed composition comprising α-lipoic compositions along with their cationic salts and other antioxidants (col. 12, lin. 19 – 30; examples).

Taking the prior art not consideration a skilled artisan would have been motivated to combine the salts of Weithmann with the composition of Ulrich in order to improve the solubility; combined the acids of Bethge and Prigal in order to properly solubilize the α-lipoic acid compounds; and would have been motivated to include the resultant formulation into a food composition as seen in Matsuoka in order to impart antioxidant properties into consumables. It would have been obvious to a skilled artisan to combine the teachings and suggestions of the art with an expected result of food product where the α-lipoic acid compound is properly solubilized and has better bioavailability, and in turn has antioxidant properties.

Response to Arguments

6. Applicant's arguments filed 1/26/04 have been fully considered but they are not persuasive. Applicant argues that:

a. Ulrich lists the other acids as auxiliary compounds and does not embrace their sustained release properties.

b. Ulrich does not exclusively teach sustained release, yet merely mentions sustained release.

7. Regarding the arguments, it is the position of the examiner that the prior art does in fact anticipate and render the claimed invention obvious. The generic claim requires a cationogenic polymer, lipoic acid and at least another acid. No guidance is given to the amounts or concentrations that are held as patentably distinct by applicant. Ulrich discloses a formulation comprising such components, and suggests the formulation can be delivered in sustained release dosage form. The limitations of the claims have been met. Applicant argues that Ulrich does not disclose that the acids f Ulrich, do not lead to interactions with polymers, yet these limitations or features are not claimed. The method only requires mixing, homogenizing, wet granulation, and drying. These limitations are too met by Ulrich. The formulations of Ulrich are mixed, homogenized, granulated and dried at temperatures between 20 and 80°C. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In further response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., interactions of acids and polymers; improved absorption of lipoic acid) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Burden is shifted to applicant to provide evidence to the criticality of the claimed limitations along with a showing of unexpected results due to those limitations. Applicant has yet to distinguish the claimed invention from the prior art, and therefore the claims will remain obviated and anticipated by the prior art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

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